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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,234	09/25/2006	Stephen Robert Wedge	056291-5304	1864

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MORGAN LEWIS & BOCKIUS LLP
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EXAMINER

RAE, CHARLESWORTH E

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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06/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,234	Applicant(s) WEDGE, STEPHEN ROBERT	
	Examiner CHARLESWORTH RAE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/17/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 19-23 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response, received 3/17/0, to the restriction/election requirements, mailed 10/17/07, electing invention I and AZD2171 and docetaxel as the composition species, is acknowledged.

Applicant's statement that claims 10 and 19-23 are readable on the elected species is acknowledged.

Status of the Claims

Claims 10, 12-24 are currently pending in this application.

Claims 1-9, and 11 are canceled.

Claims 12-18 and 24 are withdrawn for being directed to non-elected subject matter.

Claims 10, and 19-23 are presented for examination.

Amendments

Applicant's preliminary claim amendment filed 3/17/08 is acknowledged.

Applicant's statement no new matter has been added by amendment is acknowledged and made of record (see applicant's Response, received 3/17/08, at pages 6-8).

Restriction/Election

Applicant's response to the restriction/election requirements is considered to be without traverse because applicant has failed to proffer arguments pointing out any error in said restriction/election requirements.

The restriction/election requirements are made final.

Foreign Priority

Receipt of applicant's certified copy of the foreign priority application, received 9/25/06, is acknowledged.

Objection

Claim 22 is objected to for use of improper Markush claim language (see MPEP 2173.05(h)).

It is suggested that this objection may be overcome by amending the claim to recite "the group consisting of" immediately following the term "from", but before the term "paclitaxel."

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 19, 20, and 21 recite the term "AZD2171," but fails to state the full meaning of the term at the first occurrence the term is recited in the claim. This limitation is vague and indefinite because it is not clear what "AZD2171" means. It is suggested that this specific rejection may be overcome by either replacing the term "AZD2171" with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of the term "AZD2171" in the claim.

Claims 22 and 23 are rejected for the same reason as these claims fail to correct the deficiency of the claim from which they depend.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 19-23 are rejected under 102(b) as being anticipated by Stokes et al. (WO 00/47212; equivalent to US Patent 7,074,800).

No patentably weight is being given to the salt form of AZD2171 (e.g. claim 20 recites "maleate salt").

Stokes et al. (US Patent 7,074,800) teach compositions comprising certain angiogenesis inhibitors, including AZD2171, or a pharmaceutically acceptable salt thereof, in association with a pharmaceutically acceptable excipient or carrier (see reference claims 12, and 25). Instant claims 10, 19, 20, and 21 recite the terms "AZD2171," "a pharmaceutically acceptable salt thereof," and "a pharmaceutically acceptable excipient or carrier," which overlap with the teaching of Stokes (see reference claims 12, and 25). Stokes et al. teach antiangiogenic compounds, including AZD2171 (see reference claim 12), or pharmaceutically acceptable salts, for use in the manufacture of medicament for producing an antiangiogenic and/or vascular permeability reducing effect in a warm-blooded animal such as a human being (see also

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col. 62, lines 1-35). Stokes et al. teach that in the field of oncology, it is normal practice to use a combination of different forms of treatment to treat each patient with cancer (col. 62, lines 42-45). Stokes et al. teach that conjoint treatment with surgery, radiotherapy or chemotherapy may be achieved by way of the simultaneous, sequential or separate administration of the individual components of the treatment (col. 62, line 36 to col. 63, line 32, especially, col. 62, lines 40-42). In particular, Stokes et al. disclose antiproliferative/antineoplastic agents such as taxoid like taxol and taxotere (also known as docetaxel) to be suitable for use in combination with said antiangiogenic compounds (col. 63, lines 11-32, especially line 23). The following terms overlaps with the teaching of Stokes et al.: "a taxane" as recited in claim 10; "docetaxel" as recited in claims 22 and 23.

For the above reasons, claims 10 and 19-23 are found to be anticipated by the cited prior art.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Alternatively, claims 10 and 19-23 are rejected under 103(a) as being unpatentable over Stokes et al. (WO 00/47212; equivalent to US Patent 7,074,800).

The above discussion of Stokes et al. in connection with the rejection under 102(b) is incorporated by reference.

To reiterate in part, Stokes et al. (US Patent 7,074,800) teach compositions comprising certain angiogenesis inhibitors, including AZD2171, or a pharmaceutically acceptable salt thereof, in association with a pharmaceutically acceptable excipient or carrier (see reference claims 12, and 25). Stokes et al. teach antiangiogenic compounds, including AZD2171 (see reference claim 12), or pharmaceutically acceptable salts, for use in the manufacture of medicament for producing an antiangiogenic and/or vascular permeability reducing effect in a warm-blooded animal such as a human being (see also col. 62, lines 1-35). Stokes et al. teach that in the field of oncology, it is normal practice to use a combination of different forms of treatment to treat each patient with cancer (col. 62, lines 42-45). Stokes et al. teach that conjoint treatment with surgery, radiotherapy or chemotherapy may be achieved by way of the simultaneous, sequential or separate administration of the individual components of the treatment (col. 62, line 36 to col. 63, line 32, especially, col. 62, lines 40-42). In particular, Stokes et al. disclose antiproliferative/antineoplastic agents such as taxoid like taxol and taxotere to be suitable for use in combination with said antiangiogenic compounds (col. 63, lines 11-32, especially line 23).

Based on the teaching of Stokes, someone of skill in the art would have been motivated to create the instant claimed inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 19-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending application 10/563,439; claim 11 of copending application 11/663,912; claims 1-9 and 13-14 of copending application 11/994,824; claim 17 of copending application 10/594,235; and claims 9 and 11 of copending application 10/594,233, in view of Stokes et al. (WO 00/47212; equivalent to US Patent 7,074,800). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

Each of the above cited copending applications are directed to compositions comprising AZD2171.

The above discussion of Stokes et al. in connection with the rejection under 103(a) is incorporated by reference.

For the reasons stated above, claims 10 and 19-23 are deemed to be obvious variants of the limitations of the claimed subject matter of the above cited copending applications in view of Stokes et al.

These rejections are provisional obviousness-type double patenting rejections because the conflicting claims of the copending applications have not in fact been patented.

Relevant Art of Record

The below cited art made of record and relied upon are considered pertinent to applicant's invention.

Zasloff et al. (US Patent 6,596,712) teach that antiangiogenic agents are particularly useful in combination because they are not likely to cause resistance

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development since they do not act on the tumor, but on normal host tissue (see col. 2, line 36 to col. 3, line 6, especially col. 3, lines 3-6). Zasloff et al. also teach that combination of drugs with different mechanism of action is an accepted method of treatment which prevents development of resistance by the treated tumor (col. 2, line 65 to col. 3, line 3). Zasloff et al. suggest that addition of an angiogenesis inhibitor may be beneficial in combination with a platinum agent and a taxane such as docetaxel for treating advanced ovarian cancer (col. 4, lines 1-25).

Li et al. (US Patent 5,977,163) is cited disclosing that docetaxel is also known as taxotere (see abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11 June 2008
Examiner /C.R./

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614